Goa, 3rd April, 1969 (Chaitra 13, 1891)

SERIES I No. 1

सत्यमेव जयते

SUBSCRIPTION RATES — ASSINATURA

	Yearly (Anual)	Half-Yearly (Semestral)	Quarterly (Trimestral)
All 3 series (As 3 séries)	Rs. 40/-	Rs. 24/-	Rs. 18/-
I Series	Rs. 20/-	Rs. 12/-	Rs. 9/-
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GOVERNMENT GAZETTE

BOLETIM OFICIAL

GOVERNMENT OF INDIA

MINISTRY OF FINANCE

(Department of Revenue and Insurance)

New Delhi, dated the 15th February, 1969
26th Magha, 1890 Saka

Notification

Fin(Rev)/2-35/CE/5/421/69

Central Excise

G. S. R. — In exercise of the powers conferred by sub-rule (1) of rule 8 of the Central Excise Rules, 1944 the Central Government being satisfied that the recent floods in the State of Gujarat were in the nature of a major calamity, hereby exempts:

(i) Cement;

(ii) Asbestos Cement sheets; and

(iii) Galvanised iron sheets;

donated during the period commencing from 31st August, 1968 and ending with 30th April, 1969 for construction of huts for flood affected people in that state from the whole of the duty of excise leviable thereon:

Provided that —

(*a*) it is certified by the manufacturer of the goods in question on the relevant clearance documents that the goods are intended to be donated for relief of the flood affected people in the said State of Gujarat, without discrimination on grounds of religion, race or caste or any of them and distributed free without making any charge therefor,

(*b*) the goods are sent directly from the factory of manufacture to the Collector of the District (in which the huts are to be constructed) authorised by the State Government of Gujarat,

(*c*) the manufacturer produces before the Central Excise Officer incharge of his factory within two months of the date of removal of the goods from the factory or such extended period as the Collector of Central Excise may allow a certificate from the District Collector that the goods have been received by him.

Sd/-

A. S. BERAR

Deputy Secretary to the Government of India.

GOVERNMENT OF GOA, DAMAN AND DIU

Special Department

Notification

OSD/RRVS/14/66

In exercise of the powers conferred by the proviso to article 309 of the Constitution read with Government of India, Ministry of External Affairs letter No. F.7(11)/62-Goa dated 25th July, 1963, the Administrator of Goa, Daman and Diu is pleased to make the following rules amending the Goa Government Printing Press (Assistant Manager Post) Recruitment Rules 1966, issued under Notification dated 12th August, 1966 and published in Government Gazette Series I No. 24 dated 15th September, 1966 namely: —

1. *Short title and commencement:* — (i) These rules may be called Goa Government, Printing Press (Assistant Manager's Post) Recruitment (First Amendment) Rules 1969.

(ii) They shall come into force at once.

2. In the schedule attached to the said Notification for the existing entry in column 11 substitute:—

Promotion: —

Chief of Composing Section, Chief of Binding Section, Chief of Printing Section, Engraver and Head Clerk in the Government Printing Press with 5 years Service in the grades.

Transfer on Deputation: —

Suitable officer holding analogous post in the Central/State Government (Period deputation ordinarilly not exceeding 3 years).

3. In the Notification dated 12th August 1966 referred to above add the following as Rule 6: —

"6. *Power to relax:* Where the Lt. Governor of Goa, Daman and Diu is of the opinion that it is necessary or expedient so to do, he may, by order, for reasons to be recorded in writing and in consultation with the Union Public Service Commission, relax any of the provisions of these rules with respect to any class or category of persons/posts".

By order and in the name of the Administrator of Goa, Daman and Diu.

G. K. Bhanot
Chief Secretary

Panaji, 26th March, 1969.
5th Chaitra, 1891.

Notification

OSD/RRVS/31/66

In exercise of the powers conferred by the proviso to article 309 of the Constitution, read with the Government of India, Ministry of Home Affairs Notification No. F.1/29/68-GP dated 29th June, 1968, the Administrator of Goa, Daman and Diu is pleased to make the following rules amending the Goa, Daman and Diu Administration, Goa Medical College, Class I (Gazetted) posts Recruitment rules, 1968, issued under Notification of even number dated 5th October, 1968 and published in Government Gazette Series I, No. 33 dated 14th November, 1968 namely:—

1. *Short Title and Commencement:* — (i) These rules may be called Goa, Daman and Diu Administration, Goa Medical College Class I (Gazetted) posts Recruitment (First Amendment) Rules, 1969.

(ii) They shall come into force at once.

2. In the Schedule attached to the said Notification against the posts at Serial No. 2,

(i) In column 1 after the existing entry add: «Radiology-1»

(ii) In column 2 after the existing entry substitute: «19».

By order and in the name of the Administrator of Goa, Daman and Diu.

G. K. Bhanot
Chief Secretary

Panaji, 3rd March, 1969.
12th Phalguna, 1890.

Notification

OSD/RRVS/5(a)/67

In exercise of the powers conferred by the proviso to article 309 of the Constitution, read with the Government of India, Ministry of External Affairs letter no. F.7(11)/62-Goa dated the 25th July 1963, the Administrator of Goa, Daman and Diu is pleased to make the following rules relating to the Class III, non-ministerial non-gazetted posts under the Directorate of Industries and Mines under the Government of Goa, Daman and Diu.

1. **Short title.** — These rules may be called Goa, Government, Industries and Mines Department, Class III (non-ministerial, non-gazetted) posts Recruitment Rules 1969.

2. **Application.** — These rules shall apply to the posts specified in column 1 of the Schedule to these rules.

3. **Number, classification and scale of pay.** — The number of posts, classification of the said posts and the scales of pay attached thereto shall be as specified in columns 2 to 4 of the said Schedule.

4. **Method of recruitment, age limit and other qualifications.** — The method of recruitment to the said posts, age limit, qualifications and other matters connected therewith shall be as specified in columns 5 to 13 of the aforesaid Schedule.

Provided that,

(*a*) the maximum age limit specified in the Schedule in respect of direct recruitment may be relaxed in the case of candidates belonging to the Scheduled Castes and Scheduled Tribes and other special categories in accordance with the orders issued by the Government from time to time; and

(*b*) no male candidate, who has more than one wife living and no female candidate, who has married a person having already a wife living, shall be eligible for appointment, unless the Government, after having been satisfied that there are special grounds for doing so, exempts any such candidate from the operation of this rule.

5. These rules will come into effect from the date of the Notification and will relate to appointments to the various posts made on or after this date. An appointment made prior to this date through a duly constituted Staff Selection Board/Departmental Promotion Committee will be deemed to be a regular appointment, notwithstanding any provisions contained in these rules, and the probation period in that case will extend to six months only from the date of this notification.

By order and in the name of the Administrator of Goa, Daman and Diu.

D. V. Sawant, Under Secretary (Appointments).

Panaji, 16th January, 1969.
26th Pausa, 1890.

SCHEDULE

Name of the post	No. of posts	Classification	Scale of Pay	Whether Selection Post or non-Selection Post	Age for direct recruits	Educational and other qualifications required for direct recruits	Whether age and educational qualifications prescribed for the direct recruitments will apply in the case of promotees	Period of probation, if any	Method of recruitment whether by direct recruitment or by promotion or by deputation/transfer, and percentage of the vacancies to be filled by various methods	In case of recruitment, by promotion/deputation/transfer, grades from which promotion/deputation/transfer to be made	If a DPC exists, what is its composition	Circumstances in which U. P. S. C. is to be consulted in making recruitment
1	2	3	4	5	6	7	8	9	10	11	12	13
1. Mechanic Grade II	One	Class III (non-ministerial, non-gazetted)	Rs. 125-3--131-4-155.	Selection	30 years and below.	*Essential:* 1) Certificate Course in Mechanics from a recognised Institution preferably with practical experience of at least two years as a mechanic in a Workshop of repute. *Desirable:* Persons having Matriculation or equivalent qualification.	Not Applicable.	2 years	By direct recruitment.	Not applicable.	Not applicable.	As required under the rules.
2. Plater	Two	Do	Do	Do	Do	*Essential:* Certificate Course in Electroplating from a recognised Institution preferably with practical experience of at least two years in an Electroplating Section. *Desirable:* Persons having Matriculation or equivalent qualification.	Do	Do	Do	Do	Do	Do
3. Polisher	One	Do	Rs. 110-3--131	Do	Do	Experience in polishing of at least two years in an Electroplating Department. *Desirable:* Persons having education upto Middle Class.	Do	Do	Do	Do	Do	Do
4. Welder	One	Do	Do	Do	Do	Certificate Course in Welding from a recognised Institution with practical experience of at least 2 years as a Welder in Welding Section. *Desirable:* Persons having education upto Middle Class.	Do	Do	Do	Do	Do	Do

Notification

OSD/RRVS/11/67

In exercise of the powers conferred by the proviso to article 309 of the Constitution, read with the Government of India, Ministry of External Affairs letter no. F.7(11)/62-Goa dated the 25th July 1963, the Administrator of Goa, Daman and Diu is pleased to make the following rules relating to the recruitment to the Class III posts in the Directorate of Health Services under the Government of Goa, Daman and Diu.

1. **Short title.** — These rules may be called Goa Government, Directorate of Health Services, Class III (non-ministerial, non-gazetted) posts Recruitment Rules, 1969.

2. **Application.** — These rules shall apply to the posts specified in column 1 of the Schedule to these rules.

3. **Number, classification and scale of pay.** — The number of posts, classification of the said posts and the scales of pay attached thereto shall be as specified in columns 2 to 4 of the said Schedule.

4. **Method of recruitment, age limit and other qualifications.** — The method of recruitment of the said posts, age limit, qualifications and other matters connected therewith shall be as specified in columns 5 to 13 of the aforesaid Schedule.

Provided that,

(*a*) the maximum age limit specified in the Schedule in respect of direct recruitment may be relaxed in the case of candidates belonging to the Scheduled Castes and Scheduled Tribes and other special categories in accordance with the orders issued by the Government from time to time; and

(*b*) no male candidate, who has more than one wife living and no female candidate, who has married a person having already a wife living, shall be eligible for appointment, unless the Government, after having been satisfied that there are special grounds for doing so, exempts any such candidate from the operation of this rule.

5. These rules will come into effect from the date of the Notification and will relate to appointments to the various posts made on or after this date.

G. K. Bhanot
Chief Secretary

Panaji, 19th February, 1969.
30th Magha, 1890.

SCHEDULE

Name of the post	No. of posts	Classification	Scale of Pay	Whether Selection Post or non-Selection Post	Age for direct recruits	Educational and other qualifications required for direct recruits	Whether age and educational qualifications prescribed for the direct recruitments will apply in the case of promotees	Period of probation, if any	Method of recruitment whether by direct recruitment or by promotion or by deputation/transfer, and percentage of the vacancies to be filled by various methods	In case of recruitment by promotion/deputation/transfer, grades from which promotion/deputation/transfer to be made	If a DPC exists, what is its composition	Circumstances in which U. P. S. C. is to be consulted in making recruitment
1	2	3	4	5	6	7	8	9	10	11	12	13
1. Sanitary Inspector.	14	Class III (Non-ministerial non-gazetted).	Rs. 150-5-175-6-205-EB-7-240-8-256-EB-8-280.	N. A.	25 years or below.	1. Matriculation or equivalent. 2. Successful completion of sanitary Inspectors Course from a recognised Institution. 3. Knowledge of local languages. **Desirable:** Experience in Rural Health Centres/Teaching Hospital.	N. A.	Two years.	By direct recruitment.	N. A.	N. A.	As required under the rules.
2. Auxiliary Nurse Midwife.	81	Do	Rs. 110-4-150-EB-4-170-5-180.	N. A.	30 years or below.	1. Auxiliary Nurse Midwives Course from a recognised Institution. 2. Certificate in Midwifery. 3. Knowledge of local languages.	N. A.	Do	Do	Do	Do	Do

Notification

OSD/RRVS/10/66

In exercise of the powers conferred by the proviso to article 309 of the constitution read with the Government of India, Ministry of External Affairs letter No. F.7(11)/62-Goa dated 25th July, 1963, the Administrator of Goa, Daman and Diu is pleased to make the following rules amending the Goa Government, Directorate of Land Survey (non-gazetted, non-ministerial posts) Recruitment Rules 1966 issued under Notification dated 4th July, 1966 and published in Government Gazette, Series I, No. 19, dated 11th August, 1966 read with the amendment published in the Government Gazette, Series I, No. 7, dated 16th May, 1968 namely: —

1. **Short title and commencement:** —

(i) These rules may be called the Goa Government, Directorate of Land Survey (non-gazetted, non-ministerial posts) Recruitment (third amendment) Rules 1969.

(ii) They shall come into force at once.

2. In the schedule attached to the said Notification against post of Field Surveyor at serial No. 8.

(*a*) For the existing entry in column 2. substitute: "144".

(*b*) For the existing entry in column 4. substitute:

"Rs. 150-5-175-6-205-EB-7-240 (plus Theodolite allowance of Rs. 30 per mensem to those entrusted with theodolite survey work).

(*c*) For the existing entry in column 7. substitute:

"(i) S. S. C. or 5th year Lyceum or an equivalent qualification.

(ii) Persons knowing the regional languages namely Konkani/Marathi will be given preference.

Note: The candidates will be deemed to have completed satisfactorily the period of probation only after they have passed the qualifying examination for Field Surveyors held by the Land Survey Department".

G. K. Bhanot
Chief Secretary

Panaji, 1st April, 1969.
11th Chaitra, 1891.

Revenue Department

Notification

DF-894-FOR-67

In exercise of the powers conferred by Section 18 of the Wild Animals and Wild Birds Protection Act, 1965, and in pursuance of Section 19 of the said Act, the Administrator of Goa, Daman and Diu hereby notifies the following area comprising of the Reserve Forest of Bondla in Ponda Range, admeasuring 7.95 square kilometres and delimited by the boundaries mentioned below as a Game Sanctuary:—

Boundaries

North: Peak No. 150, Peak No. 107, Peak No. 260 and Peak No. 236.

South: Peak 461.

East: Peak No. 139, Peak No. 150 and Peak No. 178.

West: Peak No. 404, Peak 371, Peak No. 272, Peak No. 375 and Peak No. 284.

and further directs that the Collector of Goa, shall enquire into and determine the existence, nature and extent of any rights alleged to exist in favour of any person in or over the land comprised within the limits of such area and deal with the same as provided in the said Act.

By order and in the name of the Administrator of Goa, Daman and Diu.

W. G. Ranadive, Secretary (Revenue).

Panaji, 22nd March, 1969.
1st Chaitra, 1891.

Notification

LSG/MUN/485/68

Government Notification No. LQN 4 dated 8-1-1965 published in the Government Gazette, Series I, page 70, dated 21-1-1965, issued under section 4 of the Land Acquisition Act, 1894 in respect of the land specified in the schedule appended thereto is hereby cancelled.

By order and in the name of the Lt: Governor of Goa, Daman and Diu.

W. G. Ranadive, Secretary (Revenue).

Panaji, 25th March, 1969.
4th Chaitra, 1891.

Labour and Information Department

Mormugao Port Trust

Notification

MPT/IGA(E. 986)/69

As required under Section 124(1) of the Major Port Trusts Act, 1963, it is hereby notified that the Central Government vide Ministry of Transport and Shipping's letter No. 7-PE(28)/67 dated the 7th February, 1969, have accorded approval to the amendments to the Mormugao Port Employees' (Contributory Provident Fund) Regulations, 1965 and the Mormugao Port Employees' (Contributory Provident Fund Special Contribution) Regulations, 1966 published in the Government Gazettes Nos. 34

and 35, Series I, dated the 21st and 28th November, 1968 respectively.

The amendments will be effective from the 1st August, 1967.

By order,

Shivakumar Dhindaw
Secretary

Mormugao, 27th February, 1969.

Notification

MPT/2-GA(10)/69

In exercise of the powers conferred under Chapter VI of the Major Port Trusts Act, 1963 and with the prior sanction of the Central Government, as required under Section 52 of the said Act, the following is added as Serial No. 129 to the Schedule of Harbour and Railway Rates, published in the Bulletin Official No. 21, Series I, dated 31-5-1962 as amended from time to time.

Item No. 129 —	Way-leave Charges.	Rs. 3.25 per 10 square metres or part thereof per month or part thereof the total being rounded off to the next higher rupee.

Note. — Area for this purpose be arrived at taking into account the external diameter of the pipeline plus 30 centimetres as working space as the width and the length of the pipeline.

By order,

Shivakumar Dhindaw
Secretary

Mormugao, (Goa), 28th February, 1969.

Notification

MPT/IGA(E.1024)/69

As required under Section 124(1) of the Major Port Trusts Act, 1963, it is hereby notified that the Central Government vide Ministry of Transport and Shipping's letter No. 7-PE(6)/69 dated the 26th February, 1969, have accorded approval to the amendment to the Mormugao Port Employees (Conduct) Regulations, 1964 published in the Government Gazettes Nos. 42 and 43 (Series I), dated the 16th and 23rd January, 1969, respectively.

The amendment will be effective from the date of publication of this notification.

By order,

Shivakumar Dhindaw
Secretary

Mormugao, (Goa), 8th March, 1969.

Public Health Department

Notification

A-9/68-DHS/9731

Government of India, Ministry of Health, Family Planning and Urban Development (Department of Health and Urban Development) Notification No. F.1-20/60-Drugs dated 26th October 1968, published in the Gazette of India Part II, Section 3, Sub-section (ii), to amend further «Drugs and Cosmetics Rules 1945» is hereby re-produced below for general public information.

By order and in the name of the Administrator of Goa, Daman and Diu.

B. Ram, Secretary, Public Health Department.

Panaji, 1st February, 1969.

Notification

In exercise of the powers conferred by section 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, the same having been previously published, as required by the said sections, namely: —

1. These rules may be called the Drugs and Cosmetics (Third Amendment) Rules, 1968.

2. In the Drugs and Cosmetics Rules, 1945, (hereinafter referred in as the said Rules),

in rule 69-A, after sub-rule (3), the following sub-rule shall be added, namely: —

(4) If the licencing authority is satisfied that a loan licence is defaced, damaged or lost or otherwise rendered useless, he may, on payment of a fee of Rupees twenty five issue a duplicate licence.

3. For rule 74 of the said rules, the following rule shall be substituted, namely;

«74-*Conditions of licence in Form 25:* — A licence in Form 25 shall be subject to the conditions stated therein and to the following further conditions, namely: —

(*a*) the licensee shall provide and maintain staff, premises and equipment as specified in rule 71;

(*b*) the licensee shall comply with the provisions of the Act and of these rules and with such further requirements if any, as may be specified in any rules subsequently made under Chapter IV of the Act: provided that where such further requirements are specified in the rule, these would come into force, for months after publication in the Official Gazette.

(*c*) the licensee shall either in his own laboratory or in any other laboratory approved by the licensing authority test each batch or lot of the raw material used by him for the manufacture of his products and also each batch of the final product and

shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U. The records or registers shall be retained for a period of *five years* from the date of manufacture.

(*d*) the licensee shall keep records of the details of manufacture as per particulars given in Schedule U of each batch of the drugs manufactured by him and such records shall be retained for a period of five years.

(*e*) the licensee shall allow an Inspector, authorised by the licensing authority in that behalf, to enter, with or without prior notice, any premises and to inspect the plant and the process of manufacture and the means employed in standardising and testing the drugs.

(*f*) the licensee shall allow an Inspector, authorised by the licensing authority under the provisions of clause (e) to inspect all registers and records maintained under these rules and to take samples of the manufactured drugs and shall supply to such Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and the rules thereunder have been observed.

(*g*) the licensee shall from time to time, report to the licensing authority any changes in the expert staff responsible for the manufacture or testing of the drugs and any material alterations in the premises or plant used for the purpose which have been made since the date of the last inspection made on behalf of the licensing authority.

(*h*) the licensee shall on request furnish to the licensing authority or such authorities, as the licensing authority may direct, from every batch of the drug, or from such batch or batches of drugs as the licensing authority may from time to time specify, a sample of such quantity as the authority may consider adequate for any examination and if required full protocols of the tests which have been applied.

(*i*) If the licensing authority so directs and if requested by the licensee who had also furnished primafacie reasons for such directions, the licensee shall not sell or offer for sale any batch in respect of which a sample is or protocols are furnished under clause (h) untill a certificate authorising the sale of the batch has been issued to him by or on behalf of the licensing authority.

(*j*) the licensee shall on being informed by the licensing authority that any part of any batch of the drugs has been found by the licensing authority not to conform with the standard of strength, quality or purity specified in these rules and on being directed so to do, withdraw the remainder of the batch from sale and, so far as may in the particular circumstances of the case be practicable, recall all issue already made from that batch.

(*k*) the licensee shall maintain an Inspection Book in form 35 to enable an Inspector to record his impressions and the defects noticed,»;

4. In rule 74-A of the said rules,

(i) for clause (*d*), the following clause shall be substituted namely: —

(*d*) «The licensee shall comply with the provisions of the Act and of these rules and with such further requirements, if any, as may be specified in any rules subsequently made under Chapter IV of the Act; Provided that where such further requirements are specified in the rules, these would come into force four months after publication in the Official Gazette.

(ii) for clause (*f*),the following clause shall be substituted, namely: —

(*f*) The licensee shall, either in his own laboratory or, in any other laboratory approved by the Licensing Authority, test each batch or lot of raw materials used by him for repacking and also each batch of the product thus repacked and shall maintain records or registers shall be retained for a period of *five years* from the date of repacking. The licensee shall allow the Inspector to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and these rules have been observed.

5. After rule 74-A of the said rules, the following rule shall be inserted, namely: —

«74-B:» *Conditions of licence in Form 25-A:*

(1) The licence in Form 25-A shall be deemed to be cancelled or suspended, if the licence owned by the licensee in Form 25 whose manufacturing facilities have been availed of by the licensee is cancelled or suspended as the case may be, under these rules.

(2) The licensee shall comply with the provisions of the Act and of these rules and with such further requirements if any, as may be specified in any rules subsequently made under Chapter IV of the Act, provided that where such further requirements are specified in the rules, these would come into force four months after publication in the Official Gazette.

(3) The licensee shall test each batch or lot of the raw material used by him for the manufacture of his products and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests as pecified in Schedule U. The records or registers shall be retained for a period of five years from the date of manufacture. The licensee shall allow an Inspector to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and these rules have been observed.

(4) The licensee shall either (i) provide and maintain to the satisfaction of the licensing authorities adequate staff and adequate laboratory facilities for carrying out

tests of the strength, quality and purity of the substances manufactured by him or (ii) make arrangements with some institution approved by the licensing authority for such tests to be regularly carried out on his behalf by the institution.

6. In rule 75-A of the said rules, after sub-rule (3), following sub-rule shall be inserted, namely: —

«(4) If the licensing authority is satisfied that a loan licence is defaced, damaged or otherwise rendered useless, he may, on payment of a fee of rupees seventy-five, issue a duplicate licence»;

7. In rule 78 of the said rules,

(i) for clause (*c*), the following clause shall be substituted, namely: —

(*c*) (i) The licensee shall maintain records of manufacture as per particulars given in Schedule U.

(ii) The licensee shall either in his own laboratory or in any laboratory approved by the licensing authority test each batch or lot of the raw material used by him for the manufacture of his product and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U. The records or registers shall be retained in the case of a substance for which a potency date is fixed for a period of two years from the expiry of such date, and in the case of other substances for a period of five years from the date of a manufacture.

(ii) for clause (*k*), the following clause shall be substituted, namely: —

«(*k*) the licensee shall comply with the provisions of the Act and of these rules and with such further requirements, if any, as may be specified in any rules subsequently made under chapter IV of the Act, provided that where such further requirements are specified in the rules, those would come into force four months after publication in the Official Gazette».

8. After rule 78 of the said Rules, the following rule shall be inserted, namely: —

«78-A 'Conditions of Licence in Form 28-A'

(1) The licensee in Form 28-A shall be deemed to be cancelled or suspended, if the licence owned by the licensee in Form 28 whose manufacturing facilities have been availed of by the licensee is cancelled or suspended, as the case may be, under these rules.

(2) The licensee shall comply with the provisions of the Act and of these rules and with such further requirements if any, as may be specified in any rules subsequently made under chapter IV of the Act, provided that where such further requirements are specified in the rules, those would come into force four months after publication in the Official Gazette.

(3) The licensee shall test each batch or lot of the raw material used by him for the manufacture of his products and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U. Records or registers shall be retained, in the case of a substance for which a potency date is fixed, for a period of two years from the expiry of such date and in the case of other substances, for a period of five years from the date of manufacture. The licensee shall allow an Inspector to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and these rules have been observed.

(4) The licensee shall either (i) provide and maintain to the satisfaction of the licensing authority adequate staff and adequate laboratory facilities for carrying out tests of the strength, quality and purity of the substances manufactured by him or (ii) make arrangements with some institution approved by the licensing authority for such tests to be regularly carried out on his behalf by the institution.

9. After Schedule T of the said rules, the following schedule shall be added, namely: —

"SCHEDULE U"

(See Rules 74, 74A, 74B, 78 and 78-A)

I. Particular to be shown in manufacturing records

A. *Substances other than Parenteral Preparation in general.*

1. Serial Number.

2. Name of the product.

3. Lot/Batch size.

4. Lot/Batch Number.

5. Date of commencement of manufacture and date when manufacture was completed.

6. Names of all ingredients, quantities required for the lot/batch size, quantities actually used. (All weighing and measurements shall be checked and initialled by the competent person in the Section).

7. Control reference number in respect of raw materials used in formulation.

8. Date of mixing in case of dry products e. g. powder/ /mixture for capsule products etc.

9. Date of granulation wherever applicable.

10. Weight of granules.

11. Date of compression in case of tablets/date of filling in case of capsules.

11A. Dates of coating wherever applicable.

12. Records of test to be carried out in case of tablets as under: —

a) Average weight every thirty minutes.

b) Disintegration time as often as practicable.

13. Records of readings taken to check weight variation in case of capsules.

14. Reference to Analytical Report number stating whether of standard quality or otherwise.

15. Records on the disposal of rejected batches and batches withdrawn from the market.

16. Actual production and packing particulars indicating the size and quantity of finished packings.

17. Date of release of finished packing for distribution or sale.

18. In case of Hypodermic tablets and opthalmic preparation which are required to be manufactured under aseptic

condition, records shall be maintained indicating the precautions taken during the process of manufacture to ensure that aseptic conditions are maintained.

19. Signature of the Expert Staff responsible for the manufacture.

B. *Parenteral Preparations.*

1. Serial Number.

2. Name of the product.

3. Lot size.

4. Batch Number (if bulk lot is divided into various batches and processed separately, a batch number distinctly different from that of the bulk lot should be assigned to each of the processed batch).

5. Date of commencement of manufacture and date of completion.

6. Name of all ingredients, quantities required for the lot size, quantities actually used. (All weighings and measurements shall be checked and initialled by the competent person in the section.

7. Control reference numbers in respect of raw material used.

8. PH of the Solution wherever applicable.

9. Date and methods of filtration.

10. Sterility test reference on bulk batch wherever applicable (if bulk lot is divided into various batches and processed separately, a batch number distinctly different from that of the bulk lot should be assigned to each of the processed batch).

11. Date of filling.

12. Records of tests employed: —

a) To ensure that sealed ampoules are leak-proof.

b) To check the presence of foreign particles.

c) For pyrogens wherever applicable.

13. Records of sterilisation in case of parenteral preparations which are heat sterilised including particulars of time, temperature and pressure employed.

14. Number and size of containers filled and number rejected.

15. Reference to Analytical Report numbers stating whether of standard quality or otherwise.

16. Records of the disposal of rejected batch and batches withdrawn from the market.

17. Actual production and packing particulars.

18. Date of release of finished packings for distribution or sale.

19. Particulars regarding the precautions taken during manufacture to ensure that aseptic conditions are maintained.

20. Control reference numbers in respect of the lot of glass containers used for filling.

21. Signature of the Expert Staff responsible for manufacture.

II. Records of raw materials

Records in respect of each raw material shall be maintained indicating the quality received, control reference number, the quantities issued from time to time, the names and batch Nos. of the products for the manufacture of which the quantities have been issued and the particulars relating to the proper disposal of the stocks.

III. Particulars to be recorded in the analytical records

A. *Tablets and capsules.*

1. Analytical report number.

2. Name of the sample.

3. Date of receipt of sample.

4. Batch/Lot number.

5. *Protocols of tests applied.*

a) Description.

b) Identification.

c) Uniformity of weight.

d) Uniformity of diameter (if applicable).

e) Disintegration test (time in minutes).

f) Any others tests.

g) Results of essay.

Notes: — Records regarding various tests applied (including reading and calculations) should be maintained and necessary reference to these records should be entered in Column 5 above whenever necessary.

6. Signature of the analyst.

7. Opinion and signature of the approved analyst.

B. *Parenteral Preparations.*

1. Analytical report number.

2. Name of the sample.

3. Batch number.

4. Date of receipt of sample.

5. Number of container filled

6. Number of container received.

7. Protocols of tests applied.

a) Clarity.

b) PH wherever applicable.

c) Identification.

d) Volume in container.

e) Sterility. — (i) Bulk sample wherever applicable. (ii) container sample.

f) Pyrogen test wherever applicable.

g) Toxicity test wherever applicable.

h) Any other tests.

i) Results of assay.

Note: — Records regarding various tests applied (including reading and calculations) should be maintained and necessary reference to these records should be entered in column 7 above, wherever necessary.

8. Signature of the analyst.

9. Opinion and signature of the approved analyst.

Pyrogen test.

1. Test report number.

2. Name of the sample.

3. Batch number.

4. Number of rabbits used.

5. Weight of each rabbit.

6. Normal temperature of each rabbit.

7. Mean initial temperature of each rabbit.

8. Dose and volume of solution injected into each rabbit and time of injection.

9. Temperature of each rabbit noted at suitable intervals.

10. Maximum temperature.

11. Response.

12. Summed response.

13. Signature of the analyst.

14. Opinion and signature of the approved analyst.

Toxicity test.

1. Test report number.

2. Name of the sample.

3. Batch number.

4. Number of mice used and weight of each mouse.

5. Strength and volume of the drug injected.

6. Date of injection.

7. Results and remarks.

8. Signature of analyst.

9. Opinion and signature of the approved analyst.

C. *For other drugs.*

1. Analystical report number.

2. Name of the sample.

3. Batch/Lot number.

4. Date of receipt of sample.

5. Protocols of test applied.

a) Description.
b) Identification.
c) Any other tests.
d) Results of assay.

Note: — Particulars regarding various tests applied (including readings and calculations) shall be maintained and necessary reference to these records shall be entered in Column 5 above, wherever necessary.

6. Signature of the Analyst.

7. Opinion and signature of the approved analyst.

D. *Raw materials.*

1. Serial number.

2. Name of the material.

3. Name of the manufacturer/supplier.

4. Quantity received.

5. Invoice/Challan number and date.

6. Protocols of tests applied.

Note: — Particulars regarding various tests applied (including reading and calculations) shall be maintained and necessary reference to these records shall be entered in Column 6 above, whenever necessary.

E. *Container, Packing material etc.*

1. Serial number.

2. Name of the item.

3. Name of the manufacturer/supplier.

4. Quantity received.

5. Invoice/Challan number and date.

6. Results of tests applied.

Note: — Particulars regarding various tests applied shall be maintained and necessary reference to these records shall be entered in Column 6 above, whenever necessary.

7. Remarks.

8. Signature of the examiner.

Note: — The foregoing provisions represent the minimum requirements to be complied with by the licensee. The licensing authority, may, however, direct the nature of records to be maintained by the licensee for such products as are not covered by the categories described above.

2. The licensing authority may permit the licensee to maintain records in such manner as are considered satisfactory, provided the basic requirements laid down above are complied with.

3. The licensing authority may at its discretion direct the licensee to maintain records for such additional particulars as it may consider necessary in the circumstances of a particular case».

L. K. MURTHY
Under Secretary to the Government of India.

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